



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1423]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's Importer's Entry Notice.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

[PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Request Regarding Importer's Entry Notice--(OMB Control Number 0910--0046)--Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (U.S.C. 381) charges the Secretary of Health and Human Services (HHS), through FDA, with the responsibility of assuring foreign origin FDA regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States meet the same requirements of the FD&C Act as do domestic products, and for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA headquarters and field inspectional personnel and the U.S. Customs Service (USCS), as the USCS is responsible for enforcing the revenue laws covering the very same products.

This collection of information gathers data for FDA-regulated products being imported into the United States and is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as domestic products.

Until October 1995, importers were required to file manual entries on OMB-approved forms which were accompanied by related documents. FDA did away with use of the paper forms effective October 1, 1995, to eliminate duplicity of information and to reduce the paperwork burden both on the import community and FDA. FDA then implemented an automated nationwide entry processing system which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 is already provided electronically by filers to USCS. Because USCS relays this data

to FDA using an electronic interface, the majority of data submitted by the entry filer need be completed only once.

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin, FDA-regulated products are offered for import, FDA is notified through USCS's Automated Commercial System (ACS) by the importer (or his/her agent) of the arrival of each entry. Following such notification, FDA reviews relevant data to ensure the imported product meets the standards as required for domestic products, decides on the admissibility of the imported product, and informs the importer and USCS of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize products listed on specific lines to enter the United States unimpeded, while other products listed in the same entry may be held pending further FDA review/action.

All entry data pass through a screening criteria program resident on a USCS computer. This screening program was developed and is maintained by FDA. This electronic screening criteria module makes the initial screening decision on every entry of foreign-origin, FDA-regulated product. Almost instantaneously after the entry is filed, the filer receives FDA's admissibility decision for each entry, i.e., "MAY PROCEED" or "FDA REVIEW."

In addition to the information collected by USCS, FDA requires four additional pieces of information that were not available from USCS's system in order to make an admissibility decision for each entry. These data elements include the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. OMB has previously approved the automated collection of these four data elements for tobacco products that filers could provide to FDA along with other entry-related information. Providing this information to FDA results in

importers receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

Since the inception of the interface with ACS, FDA's electronic screening criteria program has been applied nationwide. This eliminates issues such as "port shopping" (attempts to intentionally slip products through one FDA port when refused by another, or filing entries at a port known to receive a high volume of entries). Every electronically submitted entry line of foreign-origin, FDA-regulated product undergoes automated screening and the screening criteria can be set to be as specific or as broad as applicable; changes are immediately effective. This capability is of tremendous value in protecting the public if there is a need to immediately halt specific product from entering the United States.

If the data in this collection of information is not collected, FDA could not adequately meet its statutory responsibilities to regulate imported products, nor control potentially dangerous products from entering the U.S. marketplace.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

FDA Imported Products	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Non-Tobacco	3,406	1,089	3,709,134	.14 (8 minutes)	519,279
Tobacco	330	68	22,440	.14 (8 minutes)	3142
Total					522,421

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The hourly burden for this information collection is based on FDA's averaging of data obtained during a survey of nine representative filers nationwide and FDA's experience. For purposes of comparison of hourly burden, the filers also were requested to provide the same

information with regard to filing entries manually. FDA felt that the average time for completing either electronic or manual entries was very similar.

Based on data collected by FDA's survey of nine filers and its experience, the total annual burden to the import community to submit information electronically for 3,731,574 average annual responses was 522,421 hours. The previously OMB-approved hours per response (0.14 hours) are expected to remain the same.

This burden includes the time FDA estimates it will take respondents to compile and provide documents to FDA for those entries where FDA cannot make an admissibility decision based on the electronic data alone. Based on the survey of nine filers and FDA's past experience, FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to enable them to provide data to USCS via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with USCS.

Dated: November 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.